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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,268	07/07/2005	John L Schenk	XY-lowPressure-USNP	5591
33549 7590 02/26/2007 SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521			EXAMINER NOBLE, MARCIA STEPHENS	
			ART UNIT 1632	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			MAIL DATE 02/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,268	SCHENK ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-9, 14-16, 21-24, 27, 30, 36 and 39-64 is/are pending in the application.
- 4a) Of the above claim(s) 41-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14-16, 21-24, 27, 30, 36, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. The preliminary amendment to the claims, filed 1/31/2005, is acknowledged. This amendment amends claims 2, 53, and 57-62, cancels claims 10-13, 17-20, 25, 26, 28, 29, 34, 35, 37, and 38, and adds new claims 63 and 64. Claims 1-9, 14-16, 21-24, 27, 30-33, 36, and 39-64 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I (claims 1-9, 14-16, 21-24, 27, 30-33, 36, 39 and 40) drawn to a method of generating a sperm cell insemination sample with controlled fertility characteristics, in the reply filed on 11/28/2006 is acknowledged. As Applicant made note in their response, the original claim set, rather than the amended claim set, was used in making the restriction. However, when considering the claim set of the preliminary amendment, filed 1/31/2005, it was deemed that the groupings set forth in the restriction requirement, mailed 8/28/2006, were correct and therefore the restriction will be maintained.

Claims 41-64 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/28/2005.

Claims 1-9, 14-16, 21-24, 27, 30-33, 36, 39 and 40 are under consideration.

Information Disclosure Statement

3. The information disclosure statements were filed on 6/7/2006 and 11/28/2006. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities: The specification contains multiple tables that are designated "Table 1". See pages 10, 15, 17, and 18 for example.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9, 14-16, 21-24, 27, 30-33, 36, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant invention is drawn to a method of generating a sperm cell insemination sample, comprising obtaining a semen sample for a mammal, generating a fluid stream having flow characteristics, altering the flow characteristics of said fluid stream to adjust fluid stream pressure, entraining said sperm cells into said stream, controlling sperm cell fertility characteristics through adjustment of said fluid stream pressure, and generating a sperm cell insemination sample having sperm cell fertility characteristics (claim 1). Narrowing embodiments specify the mammal as bovine or equine, a sheath fluid stream and different compositions of said sheath fluid stream, the fluid stream pressure being between 20 and 60 psi, and the sperm cell fertility characteristics be sperm motility, sperm cell viability, pregnancy rate following insemination, cleavage rate of fertilized oocytes, and blastocyst formation rate, and that the bovine sperm concentration be between about 1×10^5 and 1×10^7 .

The specification teaches multiple examples of sorting bull sperm by flow cytometry with different fluid stream pressures and then measuring the sorted sperms for fertility characteristics. For example, the specification teaches that sperm cell sorted under 30 psi had a greater percent motility and live sperm compared to sperm cells subjected to 40 psi, and 50 psi respectively (p. 10). However, the specification discloses that cleavage and blastocysts rates were best from sperm cells subjected to 40 psi (p. 13) and that following ICSI procedures with sorted sperm cells, cleavage or blastocyst rate were no different between sperm cell subjected to 40 or 50 psi (p. 14). Therefore, the specification suggests that the effective of a fluid sheath pressure to

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control fertilization characteristics differs depending on the fertilization characteristic chosen.

However, the claims do not specify a specific fluid sheath pressure that corresponds with a specific fertilization characteristic, but instead broadly includes all of the psi disclosed in the specification to encompass any fertility characteristic.

Therefore, because the fertility characteristic depends upon a specific psi, and artisan would not know which psi to use to control any given fertility characteristic.

The art teaches sperm cells are extremely delicate cells and that the full extent of the sperm cells' sensitivities have not yet been fully explored (WO99/33956, p. 3, last par; of record) and that even though a sperm cell may appear to pass through flow cytometry with no discernable side-effect, in fact, the cells themselves may have been stressed to a point that they perform less than optimally in inseminations (p. 4, lines 1-4). WO 99/33956 also teaches that a multitude of factors may be affecting sperm cell function during sorting or during assessing a sex characteristic. The art teaches that fluid sheath composition used for sorting can affect sperm cell function and seems to be species specific. The art discloses that citrate consistency for bovine sperm is important for sperm cell viability and insemination success. In contrast equine sperm seems to be hypersensitive to citrate and therefore it is suboptimal for its use with equine sperm. They also teach that a HEPES buffer consistency is necessary for optimal function and sorting of equine sperm (p. 12 and 14).

Therefore, the art suggest that there are species specific factors that affect the success of cell sorting method to produce sperm cell that have optimal sex

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characteristics. The claims do encompass the use of some different sheath fluid compositions, however, the claims do not specify the essential element of which sheath fluid to use for a given species.

WO 99/33956 also states that an important factor to consider is that a sperm cell's stress threshold is a limiting factor in sorting sperm cells because in the case of pressure, it may be that merely subjecting the sperm cells to a higher pressure as a result of the operation of flow cytometry at that pressure may result in decreased performance and not necessarily distinguishing or controlling for a sex characteristic as claimed. The art further suggests that pre- and post-sorting handling stress can also affect sperm performance as well (par bridging p. 11-12). Therefore, it is not clear from the art if the increase in pressure is truly selecting or controlling a sex characteristic as claimed or more generically identifying sperm cell resistance to stress. Therefore, an artisan would not know if the instant method is truly sorting and controlling for a sex characteristic as claimed or more generally identifying cell resistant to the stress of pressure cause be sheath fluid pressure alterations.

Overall, because the breadth of the claims do not specify key limiting and essential elements for the specificity of the claimed method, an artisan would not be able to use the instant method. Therefore, the instant method is not enabled.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 6, 14-16, 21-23, 31, 39, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "sheath fluid stream" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 6 depends from claim 5. Claims 14, 15 and 16 recite the limitation "said bovine semen" and "said male of a bovine species of mammal". There is insufficient antecedent basis for this limitation in the claim. Although unclear for lacking antecedent basis, claims have been interpreted as referring to a bovine specific method.

Claims 21, 22, 23 recite the limitation "said equine semen" and "said male of a equine species of mammal". There is insufficient antecedent basis for this limitation in the claim. Although unclear for lacking antecedent basis, claims have been interpreted as referring to an equine specific method.

Claim 31, 39 and 40 recites the limitation "said bovine species". There is insufficient antecedent basis for this limitation in the claim. Claims 39 and 40 depend upon claim 31.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 8, 9, 24, 27, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS).

The instant invention is drawn to a method of generating a sperm cell insemination sample comprising: a.) obtaining semen from a male of a species of mammal, b.) generating a fluid stream with flow characteristics, c.) altering flow characteristics of said fluid stream to adjust fluid stream pressure, d) entraining said sperm cells into said fluid stream, e.) controlling sperm cell fertility characteristics through adjustment of said fluid stream pressure, and f.) generating a sperm cell insemination sample having controlled sperm cell fertility characteristics (claim 1). Narrowing embodiments specify species of mammal (claim 2), the fluid stream be a sheath fluid stream containing PBS (claims 3 and 4), that the fluid stream be generated by a flow cytometer or cell sorter (claim 8), that the fluid stream pressure be between about 20 psi and about 60 psi (claim 9), that the sperm cell fertility characteristic be cell motility (claim 24), viability (claim 27), or embryo cleavage rate (claim 33).

Rath et al discloses a method of sorting sperm by sex and determining its ability to generate embryos by in vitro fertilization. Their method is comprised of collecting sperm from boars (p. 3347, col 2, par 1, line 1-2), subjecting the sperm to flow cytometry, and determining the generation of embryos produced by in vitro fertilization (a measure of fertility characteristics) with sex sorted sperm or unsorted sperm (p. 3348

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in total). The flow cytometry consisted of generating a flow and entraining sperm samples into the fluid stream (p. 3348, col 1). They disclose that the fluid sheath was PBS (p. 3348, col 1). They disclosed that they adjusted the fluid stream flow through the adjustment of pressure to using high-speed sperm sorting with a fluid sheath pressure of 2.81 kg/cm^2 , which is approximately 40 psi, to improve sorting and fertility characteristics over standard speed sorting (p. 3346, col 2, lines 3-7 and p. 3348, col 1). They disclosed that sperm motility following sorting was 60% in all cases (p. 3349, col 1). They also disclose fertilization rates and cleavage rates, which also indicates that the sperm is viable and can serve as a measure of sperm viability as claimed.

8. Claims 1-3, 5-9, 14, 24, 27, 30, 31, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Seidel et al (WO 99/33956 pub date:7/8/1999; of record in IDS).

The instant invention is drawn to a method of generating a sperm cell insemination sample comprising: a.) obtaining semen from a male of a species of mammal, b.) generating a fluid stream with flow characteristics, c.) altering flow characteristics of said fluid stream to adjust fluid stream pressure, d) entraining said sperm cells into said fluid stream, e.) controlling sperm cell fertility characteristics through adjustment of said fluid stream pressure, and f.) generating a sperm cell insemination sample having controlled sperm cell fertility characteristics (claim 1). Narrowing embodiments specify species of mammal (claim 2), the fluid stream be a sheath fluid stream (claim 3) containing 2.9% sodium citrate (claims 5 and 6) or HEPES buffer (claim 7), that the fluid stream be generated by a flow cytometer or cell sorter

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(claim 8), that the fluid stream pressure be between about 20 psi and about 60 psi

(claim 9), that the sperm cell fertility characteristic be cell motility (claim 24), viability

(claim 27), pregnancy rate (claim 30), specifically bovine pregnancy rate (claim 31).

Claim 14 specifies that the species be a bovine and that stream pressure be between about 30 and about 50 psi. Narrowing embodiments specify that a bovine insemination sample be between about 1×10^5 and 2×10^7 sperm/ml (claim 39) or 1×10^6 and 3×10^6 sperm/ml (claim 40).

Seidel discloses a general method of sorting sperm (p. 9 and 10). Seidel discloses that the fluid sheath composition should be modified depending on the species of mammalian sperm. Seidel discloses that the flow cytometry for sperm sorting can be adjusted to 50 or 60 psi (p. 11, lines 22-24). Seidel discloses the use of a sheath fluid containing 2.9% sodium citrate is best when sorting bull semen (p. 13, lines 26-28) and that HEPES buffer is best when sorting equine sperm (p. 14, lines 15-16). Seidel discloses a method of measuring motility and viability in sperm (p. 20) as well.

Seidel discloses specific examples of sorting bull sperm by flow cytometry using a 2.9% sodium citrate sheath with a fluid stream pressure of 50 psi. Seidel further discloses that the sorted bovine sperm were resuspended in a concentration of 1.63×10^6 sperm/ml. Seidel discloses that these insemination samples were used to inseminate cows and then pregnancy rates were determined (p. 25).

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9. Claims 1-4, 8, 9, 14-16, 24, 27, 33, 36, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Beyhan et al (Theriogenology 53:35-48, 1999; of record).

The instant is drawn to a method of generating a sperm cell insemination sample comprising: a.) obtaining semen from a male of a species of mammal, b.) generating a fluid stream with flow characteristics, c.) altering flow characteristics of said fluid stream to adjust fluid stream pressure, d) entraining said sperm cells into said fluid stream, e.) controlling sperm cell fertility characteristics through adjustment of said fluid stream pressure, and f.) generating a sperm cell insemination sample having controlled sperm cell fertility characteristics (claim 1). Narrowing embodiments specify species of mammal (claim 2), the fluid stream be a sheath fluid stream containing PBS (claims 3 and 4), that the fluid stream be generated by a flow cytometer or cell sorter (claim 8), that the fluid stream pressure be between about 20 psi and about 60 psi (claim 9), that the sperm cell fertility characteristic be cell motility (claim 24), viability (claim 27), embryo cleavage rate (claim 33), or blastocyst rate (claim 36). Claim 14 specifies that the species be a bovine and that stream pressure be between about 30 and about 50 psi. Claim 15 specifies that the species be a bovine and that stream pressure be between about 30 and about 40 psi. Claim 16 specifies that the species be a bovine and that stream pressure be about 40 psi. Narrowing embodiments specify that a bovine insemination sample be between about 1×10^5 and 2×10^7 sperm/ml (claim 39) or 1×10^6 and 3×10^6 sperm/ml (claim 40).

Beyhan discloses a method of sorting bull sperm by flow cytometry using a fluid sheath containing PBS with a sheath fluid pressure adjusted to 40 psi (p. 37, last par). Beyhan discloses that the sorted bovine sperm were prepared and further used at a concentration of 1×10^6 sperm/ml. Sperm motility was determined before in vitro fertilization (p. 38, par 3). After in vitro fertilization, blastocyst formation rate, cleavage rate, and consequently indirect measurements of sperm viability were obtained (par bridging p. 38 and 39).

10. Claims 1-3, 8, 9, 14-16, 21-24, and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Suh and Schenk (Theriogenology 53(1):516, Jan 2003; of record).

The instant is drawn to a method of generating a sperm cell insemination sample comprising: a.) obtaining semen from a male of a species of mammal, b.) generating a fluid stream with flow characteristics, c.) altering flow characteristics of said fluid stream to adjust fluid stream pressure, d) entraining said sperm cells into said fluid stream, e.) controlling sperm cell fertility characteristics through adjustment of said fluid stream pressure, and f.) generating a sperm cell insemination sample having controlled sperm cell fertility characteristics (claim 1). Narrowing embodiments specify species of mammal (claim 2), the fluid stream be a sheath fluid stream (claims 3), that the fluid stream be generated by a flow cytometer or cell sorter (claim 8), that the fluid stream pressure be between about 20 psi and about 60 psi (claim 9), that the sperm cell fertility characteristic be cell motility (claim 24) or viability (claim 27). Claim 14 specifies that the species be a bovine and that stream pressure be between about 30 and about 50

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psi. Claim 15 specifies that the species be a bovine and that stream pressure be between about 30 and about 40 psi. Claim 16 specifies that the species be a bovine and that stream pressure be about 40 psi. Claim 21 specifies that the species be an equine and that stream pressure be between about 30 and about 50 psi. Claim 22 specifies that the species be an equine and that stream pressure be between about 30 and about 40 psi. Claim 23 specifies that the species be an equine and that stream pressure be about 40 psi.

Suh and Schenk disclose an experiment where bull sperm is subjected to three different sheath fluid pressures (30, 40 , and 50 psi) to determine the affects of differential sheath fluid pressure on sperm cell motility and viability. Suh and Scenk also disclose the same procedure was done with equine sperm. (see abstract)

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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